DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 3, 2014

Alivecor, Inc.
Albert Boniske
Director of Regulatory Affairs
30 Maiden Lane, 6th Floor
San Francisco, California 94108

Re: K142672
Trade/Device Name: Alivecor Heart Monitor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: November 3, 2014
Received: November 4, 2014

Dear Albert Boniske,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142672

Device Name: AliveCor Heart Monitor

Indications For Use:

The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.

Prescription Use X	And/Or	Over the Counter Use X
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

510(k) Notification K142672

GENERAL INFORMATION

Applicant:
AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94108

Contact Person:
Albert Boniske
Director of Regulatory Affairs
AliveCor, Inc.
Phone: 415-795-9811
Fax: 415-397-0440

Date Prepared:
September 18, 2014

DEVICE INFORMATION

Trade Name:
AliveCor Heart Monitor

Generic/Common Name:
Telephone electrocardiograph transmitter and receiver

Classification:
21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:
DXH, DPS

PREDICATE DEVICE(S)

- K140933 – AliveCor Heart Monitor

INDICATIONS FOR USE

The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.

DEVICE DESCRIPTION

The AliveCor Heart Monitor (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the processing power of a mobile computing platform (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The AliveCor Heart Monitor can also analyze ECG signals and indicate the presence of atrial fibrillation for each ECG recording.

SUBSTANTIAL EQUIVALENCE

The new AliveCor Heart Monitor is substantially equivalent to the original cleared AliveCor Heart Monitor. The new AliveCor Heart Monitor has been redesigned for aesthetic appeal and functions to the same specifications for the same intended use as the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the AliveCor Heart Monitor to support a determination of substantial equivalence to the predicate devices. The non-clinical testing included ECG performance evaluation in accordance with IEC 60601-2-47, electrical safety and EMC testing in accordance with IEC 60601-1 and 60601-1-2, and internal verification and validation testing. The collective results of the non-clinical testing demonstrate that the AliveCor Heart Monitor meets the established specifications and complies with the aforementioned standards.

CONCLUSION

The results of the nonclinical testing demonstrate that the AliveCor Heart Monitor is substantially equivalent to the predicate device.